USER MANUAL

OXYGEN PEDIATRIC FLOWMETER

MODELS: 1MFA3001 (SHOWN)
4MFA1001
6MFA1001

Authorized EU Representative:
EMERGO EUROPE, INC.
Molenstraat 15
2513 BH The Hague
NETHERLANDS

CE 0197

SAVE THESE INSTRUCTIONS

⚠CAUTION Federal (USA) law restricts this device to sale by or on the order of a physician.

PRECISION MEDICAL®

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ISO 13485 Certified

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RECEIVING / INSPECTION

Remove the Precision Medical, Inc. Flowmeter from the packaging and inspect for damage. If there is any damage, DO NOT USE and contact your Provider.

INTENDED USE

The Flowmeter is intended for use by physicians, respiratory therapists and other authorized hospital personnel to administer selected doses of medical oxygen to a patient.

READ ALL INSTRUCTIONS BEFORE USING

This manual instructs a Professional to install and operate the Flowmeter. This is provided for your safety and to prevent damage to the Flowmeter. If you do not understand this manual, DO NOT USE the Flowmeter and contact your Provider.

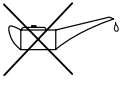
SAFETY INFORMATION - WARNINGS AND CAUTION

⚠WARNING Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

⚠CAUTION Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury.

CAUTION Used without the safety alert symbol indicates a potentially hazardous situation which, if not avoided, may result in property damage.

CONSULT ACCOMPANYING DOCUMENTS



Symbol for “USE NO OIL”

Symbol for “NO SMOKING”

⚠WARNING

- Use this Flowmeter only for its “Intended Use” as described in this manual.
- ALWAYS confirm prescribed flow before administering to patient and monitor flow on a frequent basis.
- This Flowmeter contains magnetic, ferrous material that may affect the results of an MRI.

To Reduce the Risk of Fire or Explosion:

- ALWAYS follow ANSI and CGA standards for Medical Gas Products and Flowmeters (E-7) and Oxygen Handling (G-4).
- **DO NOT** use oils, greases, organic lubricants or any combustible materials on or near this Flowmeter.
- **DO NOT** use near any type of flame or flammable/explosive substances, vapors or atmosphere.
- **DO NOT** smoke in an area where oxygen is being administered.

⚠CAUTION

- This Flowmeter must be operated with the Flow Tube in a vertical, upright position.
- Only personnel instructed and trained in its use should operate this Flowmeter.
- Be sure all connections are tight and leak free.
- Only use oxygen-safe leak detector.
- **DO NOT** autoclave.
- **DO NOT** gas sterilize with EtO (Ethylene Oxide).
- **DO NOT** clean with aromatic hydrocarbons.
- **DO NOT** immerse product in any kind of liquid. This will void the warranty.
- This Flowmeter may have a factory installed restrictor. Prior to use, check product labeling for flow restrictions.
- This Flowmeter contains a glass flowtube which is fragile. Special care should be observed to avoid braking the flowtube.

SPECIFICATIONS

Model	6MFA1001	4MFA1001	1MFA3001
Flow Range	0-200 cc	0-1 lpm	0-3 lpm
Gas	Oxygen	Oxygen	Oxygen
Increments	20 cc (starts at 20 cc)	.1 lpm (starts at .1 lpm)	.125 from .125 to 1 lpm .25 lpm from 1 to 3 lpm
Accuracy	± 10 cc from 0-100 cc ± 14 cc from 100-200 cc	± .05 lpm	± .15 lpm
Max Flush Flow Range	500 cc*	6 lpm*	20 - 40 lpm
Transport / Storage Requirements	-40˚F (-40˚C) to 140˚ (60˚C)		

* Restricted Max Flush Flow

NOTE: Storage / Transport outside the specified range may cause damage to the flowmeter.

The effect on accuracy of flow due to variations in ambient temperature is standard accuracy +7.3% @ 0°C and -3.0% @ + 40°C.
Flowmeters calibrated at 50 psi (3.4 bar), 70°F (21°C), standard atmospheric pressure.

International models are calibrated per specifications marked on Flow Tube.

Specifications are subject to change without prior notice.

OPERATING INSTRUCTIONS

⚠WARNING

Read this User Manual before installing or operating the Flowmeter.

CAUTION

Inspect the Flowmeter for visual damage before use, DO NOT USE if damaged.

NOTE: Precision Medical, Inc. strongly recommends the use of kink proof Cannula.

1. Turn Knob to the "OFF" position.
2. Connect the Flowmeter to a 50 psi oxygen gas source. For international products, connect to appropriate oxygen source pressure.
   NOTE: Attaching accessories to the outlet (which may increase resistance to outlet flow) may change indicated flow but will not affect the accuracy of the flow.
3. Verify that the Float Ball is at the very bottom of the Flow Tube.
   NOTE: If the Float is not resting at the bottom of the Flow Tube, the product is leaking; consult the Troubleshooting Guide.
4. Adjust Flow:
   To **increase** - Turn Knob **counterclockwise**
   To **decrease** - Turn Knob **clockwise**
5. Set flow by aligning center of Float Ball with indicator lines on the Flow Tube.
6. Adjusting flow beyond the last calibrated indicator line will result in an undetermined flow.
7. To obtain maximum flush flow, turn Knob fully Counterclockwise.
   NOTE: Flush flow is any flow above the last calibrated line on the Flow Tube with an unrestricted flow, as per specifications.

⚠WARNING

- **To avoid injury to patient:**
  ALWAYS confirm prescribed flow before administering to patient and monitor flow on a frequent basis.
- **DO NOT** immerse the Flowmeter in any kind of liquid. This will cause damage to the Flowmeter and will void the warranty.

CAUTION

- **DO NOT** over tighten Knob when turning off. This will cause damage to the Flowmeter.
- Pressures other than those indicated on the Flow Tube may affect the accuracy of the indicated flow.
- Gas Temperatures other than 70° F (21°C) may affect the accuracy of the indicated flow.
- ONLY use appropriate gas specific indexed fittings to connect Flowmeter to gas source. Use Oxygen connections for oxygen Flowmeters.

CLEANING INSTRUCTIONS

1. Disconnect all connections before cleaning.
2. Clean exterior surfaces of the Flowmeter with a cloth dampened with a mild detergent and water.
3. Wipe dry with a clean cloth.

TROUBLESHOOTING

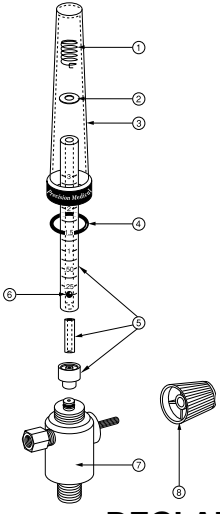
If the Flowmeter fails to function, consult the Troubleshooting Guide below. If problem cannot be corrected, consult your Provider or Precision Medical, Inc.

Problem	Probable Cause	Remedy
Will not shut off	• Leak • Defective Valve	• Replace Tetraseal and/or Housing • Replace Body Assembly
Sticking Float Ball	• Debris in Flow Tube	• Clean Flow Tube
Unable to set desired flow	• Blocked Inlet	• Replace Body Assembly
Knob will not turn	• Valve seized	• Replace Body Assembly

RETURNS

Returned products require a Returned Goods Authorization (RGA) number. Any product returned to Precision Medical, Inc. must be packaged in a sealed container to prevent damage. Precision Medical, Inc. will not be responsible for goods damaged in transit.

REPLACEMENT PARTS



	Description	Model No. 6MFA1001 0-200 cc OXYGEN 50 PSI	Model No. 4MFA1001 0-1 lpm OXYGEN 50 PSI	Model No. 1MFA3001 0-3 lpm OXYGEN 50 PSI
1	Spring	1575	1575	1575
2	Washer	1787	1787	1787
3	Housing	1143	1143	1143
4	Tetraseal™	1123	1123	1123
5	Flow Tube Kit	503213	503214	503215
6	Float Ball	1576	1576	1576
7	Body Assembly	1891	1897	502053
8	Knob	1007	1007	1007

International parts specifications and specific ratings are available upon request.
International flowmeters are calibrated per specifications on flowtube.

DECLARATION OF CONFORMITY

Manufacturer: Precision Medical, Inc.
300 Held Drive, Northampton, PA 18067, USA
CONTACT: Quality Manager
Phone: 610-262-6090

Authorized European Representative: Emergo Europe
Molenstraat 15
2513 BH, The Hague
The Netherlands

Product: Flowmeters
Model(s): 1MFA
MDD Class: IIb
Classification criteria: Clause 3.2 Rule 11 of Annex IX of MDD

As delivered, the object of the declaration described above is in conformity with the requirements of MDD 93/42/EEC Annex II.3 and the following documents:

Document	Title	Edition
BS EN 13220	Flow Metering Devices for Connection to Terminal Units of Medical Gas Pipeline Systems	1999
ISO 14971	Medical Devices - Application of risk management to Medical Devices, 2nd Edition	2000+A:1:2003
EN 980	Graphical Symbols for Use in the Labeling of Medical Devices	2003
BS EN 1041	Information supplied by the Manufacturer with Medical Devices	1998
EN ISO 15001	Anaesthetic and Respiratory Equipment - Compatibility with Oxygen	2003

Notified Body: TÜV Rheinland Products Safety GmbH CE 0197
EC Certificate No.: HD 60019110 0001

LIMITED WARRANTY AND LIMITATION OF LIABILITY

Precision Medical, Inc. warrants that the Medical Gas Flowmeter (the Product) will be free of defects in workmanship and/or material for the following period:

(a)	Housing	Lifetime of the product
(b)	Needle Valve	Five (5) years from shipment
(c)	All other parts of the Medical Gas Flowmeter not identified in (a) or (b) above	One (1) year from shipment

Should any failure to conform to this warranty appear within the applicable period, Precision Medical, Inc. shall, upon written notification thereof and substantiation that the goods have been stored, installed, maintained and operated in accordance with Precision Medical, Inc.'s instructions and standard industry practice, and that no modifications, substitutions, or alterations have been made to the goods, correct such defect by suitable repair or replacement at its own expense.

ORAL STATEMENTS DO NOT CONSTITUTE WARRANTIES.

The representative of Precision Medical, Inc. or any retailers are not authorized to make oral warranties about the merchandise described in this contract, and any such statements shall not be relied upon and are not part of the contract for sale. Thus, this writing is a final, complete and exclusive statement of the terms of that contract.

THIS WARRANTY IS EXCLUSIVE AND IS IN LIEU OF ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR OTHER WARRANTY OF QUALITY, WHETHER EXPRESS OR IMPLIED.

Precision Medical, Inc. shall not under any circumstances be liable for special, incidental or consequential damages including but not limited to lost profits, lost sales, or injury to person or property. Correction of non-conformities as provided above shall constitute fulfillment of all liabilities of Precision Medical, Inc. whether based on contract, negligence, strict tort or otherwise. Precision Medical, Inc. reserves the right to discontinue manufacture of any product or change product materials, designs, or specifications without notice.

Precision Medical, Inc. reserves the right to correct clerical or typographical errors without penalty.